

Response to Arguments

Applicant's arguments filed May 9, 2008 have been fully considered but they are not persuasive. Applicant's arguments suggest that the prior art references must provide teaching and suggestion of sharing a power supply between elements of the handpiece; specifically of the powered surgical device and the detachable tracker. The examiner contends that the use of a common power unit would be a common sense decision of a skilled artisan to reduce weight and complexity of the device. Advances in battery design, size and weight would contribute to the motivation for such a combination.

This thinking is substantiated by KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL.; SUPREME COURT OF THE UNITED STATES, No. 04-1350; ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT; April 30, 2007.

"Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM (teaching, suggestion motivation) test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.

"We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes

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even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts. See U. S. Const., Art. I, §8, cl. 8. These premises led to the bar on patents claiming obvious subject matter established in *Hotchkiss* and codified in §103. Application of the bar must not be confined within a test or formulation too constrained to serve its purpose."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 71-73, 76, 79, 80, 89-93, 95, 99-101 and 103-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2001/0034530 to Malackowski et al. in view of U.S. Patent 5,873,814 to Adair. Malackowski et al. teach a

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surgical system that includes a handpiece (Fig. 1, # 102) referred to as a smart instrument and a surgical navigation system. The smart instrument may be any number of common surgical instruments that may be tracked by attachment to the universal tracker device (Fig. 3, # 200), including but not limited to a probe, scalpel, suction device, pin, or clamp. In order to couple the tracker device to the general instrument, an adapter is connected to the adapter interface of the universal tracker device and the general instrument is attached by a clamp screw (paragraph 0070). This clearly teaches a removable tracking unit. The means for attaching the tracking unit to the handpiece or surgical instrument is considered an obvious design consideration for one of skill in the art; as such attachment means are pervasive and predictable. The smart instrument may also store the specific geometry of the active part of the smart tool, i.e., the tip or the part of the tool that is in contact with the patient or delivering some kind of energy, mechanical, electrical, sonic, electromagnetic, etc. (paragraph 0080), thus teaching a unit that consumes power and in the case of mechanical energy, implies a bit or cutter that is interpreted as an accessory. Such cutters require a motor. The tracker device includes a plurality of infrared light emitting diodes, a communication transceiver (wireless receiver), and a status light. The smart instruments and the navigation system transceivers communicate via infrared (light energy) signals, although other types of wireless technologies may also be used (paragraph 0059). The properties of the smart instruments, such as geometry and functional features, are preferably graphically displayed on the computer monitor to enable visual display of their spatial and functional relationships to other smart instruments, surgical equipment, and the surgical field (Figs. 25-32). While Malackowski et al. teach a display of the positional information, it is not on the handpiece. Adair discloses an endoscope with a handpiece portion onto which is mounted a flat display and further teaches the communications with the display may be wireless (Col. 2, lines 50-54). The video monitor provides a means by which a surgeon

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may conveniently position a video image of the surgical site in visual alignment with the surgical area, thus the surgeon's ability to manipulate an instrument is greatly enhanced and fatigue is reduced (Col. 15, lines 15-25). Therefore it would have been obvious to one skilled in the art to position the positional information display on the handpiece as taught by Adair in the invention of Malackowski et al. to provide line of sight visualization and reduced fatigue to the operator.

The battery of the tracker and the smart instruments is preferably a lithium battery (paragraph 0069). It is inherent that a power connector be included. The smart instrument of Malackowski et al. may be any electrical power consuming device, which could include low power LED or semiconductor laser devices. The examiner takes the position that a skilled artisan would provide power as appropriate for the devices in the handpiece making this an obvious design choice. Clearly, a skilled artisan would consider the power requirements of the instrument and the impact of a current surge from a high current instrument on other items on a common source. The Applicant teaches the power supplies may be common or separate, thus supporting this position. A skilled artisan would also consider advances in battery and display technology in handpiece design, thus making an LED display a logical and obvious choice.

Claims 75, 78, 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2001/0034530 to Malackowski et al. in view of U.S. Patent 5,873,814 to Adair as applied to claims 71 and 89 above and further in view of U.S. Patent Application Publication US 2002/0035321 to Bucholz et al. Malackowski et al. are discussed above, but do not teach a drill bit with coupling. Bucholz et al. disclose a system for use during a surgical procedure on a body. Using a navigation system (Fig. 11), the positioning of an instrument relative to a body can be displayed. One instrument that is used commonly is a drill. By placing emitters (tracking member) on a surgical drill (handpiece), and by having a fixed relationship between the drill body and its tip (usually a drill bit), the direction and position

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of the drill bit can be determined. The drill bit is interpreted as an accessory (and distal end) and such a bit inherently moves as it rotates and is coupled with a chuck (paragraph 0103). It would have been obvious to one skilled in the art to use the drill as taught by Bucholz et al. in the surgical device of Malackowski et al. and Adair as the use of such cutting instrument is well known and common in the art.

Allowable Subject Matter

Claims 102 and 105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3739

/HMJ/
6/9/2008